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EXAMINER	
SCHMIDTMANN, BAHAR	

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
04/01/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/537,118	BEAUDET ET AL.	
	Examiner	Art Unit	
	BAHAR SCHMIDTMANN	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-34,39 and 40* is/are pending in the application.

4a) Of the above claim(s) *7-18,20-28,31-34 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-6,19,29,30 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/18/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's Amendment and Remarks filed on 18 December 2009 in which claims 2-3 and 35-38 were canceled and claim 1 was amended to change the scope and breadth of the claims.

Claims 1, 4-34 and 39-40 are pending in the current application. Claims 31-34 and 39 remain withdrawn as being drawn to a nonelected invention. Claims 7-18 and 20-28 remain withdrawn as being drawn to a nonelected species. Claims 1, 4-6, 19, 29, 30 and 40 are examined on the merits herein.

Election/Restrictions

To facilitate prosecution, the species of election for active molecule has been modified to include 5-fluorouracil (5-FU).

Applicant's election with traverse of Group I, claims 1-30 and newly added claim 40 in the reply filed on 29 July 2009 is acknowledged. The requirement was made final in the previous Office Action.

Information Disclosure Statement

The Information Disclosure Statement submitted 18 December 2009 is acknowledged and considered.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-6, 19, 29, 30 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "micelles comprising exopolysaccharide" in claim 1 renders the claim and its dependent claims herein indefinite. It is unclear if the composition comprises a micelle that is distinct from the exopolysaccharide or if the micelle is the exopolysaccharide.

If the micelles of the instant invention are in fact the exopolysaccharides, then claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. Micelles are known to be composed of a hydrophilic and a hydrophobic moiety. However, the claim only recites a polysaccharide, which is most likely the hydrophilic portion. In order for a micelle to exist, the polysaccharide must be attached to a hydrophobic moiety. The omitted elements are: the additional component(s), i.e. the hydrophobic moiety attached to the exopolysaccharide making up the micelle.

Claim 1 includes a Markush grouping of bacteria that includes species that are not bacteria, i.e. *Candida kefyr* and *Candida norvegensis* are considered yeasts. The

claim could be amended such that the items within the Markush grouping are within the genus "bacteria". Appropriate correction or clarification is required.

The recitation "delivery system" in claim 1 renders the claim and its dependent claims herein indefinite. The term "system" is unclear as to what category being claimed here, because this can be interpreted as either an apparatus or a composition or a method (a process) of use. For example, an apparatus in the instant application could be a stent comprising the micellar composition. On the other hand, the term "system" in the instant application could simply be synonymous with "composition", a term which is more commonly found in product claims, not device/apparatus claims. The instant specification does not define system. As a result, one having ordinary skill would not necessarily know if the instant claims are drawn to a composition/product or an apparatus/device or a method of use this product.

Applicants are suggested to amend the claims to clearly recite a product or a method of use herein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4-6, 19, 29 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Simard et al., hereafter as the '131 publication (US Application Publication No. 2006/0057131, cited in PTO-892).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The '131 publication discloses fermentation by-products produced from bacterial *Lactobacillus* strains R2C2, INIX, ES1 and K2 (claim 28). The '131 publication discloses the fermentation by-product comprises polysaccharides, including exopolysaccharides, hereafter EPS (paragraphs 0038-0039). The '131 publication discloses the protein containing the EPS is formulated at concentrations ranging from 0.001% to 1% (column 17, example 26, paragraph 0182), i.e. critical micellar concentrations identical to the instant disclosure (see instant specification, column 4, example 1, paragraph 0056). The '131 publication discloses the EPS containing protein is formulated with 5-fluoro uracil to treat colon cancer (column 20, example 37). Thus, the '131 publication discloses an EPS micelle, i.e. a "delivery system" comprising 5-FU, wherein the EPS was produced by bacterial *Lactobacillus* strains R2C2, INIX, ES1 and K2.

The disclosure of the '131 publication anticipates claims 1, 4-6, 19, 29 and 30 of the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-6, 19, 29, 30 and 40 are rejected under 35 U.S.C. 103(a) as being obvious over Simard et al., hereafter as the '131 publication (US Application Publication No. 2006/0057131, cited in PTO-892) in view of Campbell et al. (US Application Publication No. 2002/0090392, cited in PTO-892).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art

only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The '131 publication teaches as discussed above.

The '131 publication does not expressly disclose taxane as an active ingredient.

Campbell et al. teaches liposomes containing a therapeutic agent can be used to target tumors (abstract and column 1, paragraph 0007-0008). Campbell et al. teaches the therapeutic agents can include paclitaxel (taxane) as well as the antimetabolite fluorouracil (claim 8), also known as 5-Fluorouracil or 5-FU.

It would have been obvious at the time the invention was made to formulate a composition comprising a micelle, an exopolysaccharide produced from *Lactobacillus* strains R2C2, INIX, ES1 and K2 and taxane.

MPEP 2141 states, "The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "[R]ejections on obviousness cannot be sustained by mere conclusatory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" KSR, 550 U.S. at, 82 USPQ2d at 1396. Exemplary rationales that may support a conclusion of obviousness include: (A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) " Obvious to try " choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention."

Based on the teachings of the MPEP and KSR above, by employing the rationale in (B) simple substitution of one known element for another to obtain predictable results; one having ordinary skill in the art would have been motivated to formulate a composition comprising a micelle, an exopolysaccharide produced from *Lactobacillus* strains R2C2, INIX, ES1 and K2 and taxane. The '131 publication teaches a micelle comprising an EPS produced from the aforementioned strains to treat cancer, specifically with 5-FU as the therapeutic agent. Campbell et al. teaches that 5-FU and taxane are both anti-cancer agents and can be formulated with micellar structures, such as liposomes. Thus, one having ordinary skill in the art would be motivated to substitute the 5-FU taught in the '131 publication for taxane since they are taught as having similar functionality in similar formulations.

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teaching of the prior art.

Claims 1, 4-6, 19, 29, 30 and 40 are rejected under 35 U.S.C. 103(a) as being obvious over Abraham et al. (*Journal of Dairy Research*, cited in PTO-892) as evidenced by Micheli et al. (*Applied Microbiology and Biotechnology*, cited in PTO-892) and Maeda et al. (*Journal of Agricultural Food Chemistry*, cited in PTO-892) in view of Jolly et al. (*Antonie van Leeuwenhoek*, cited in PTO-892) and Campbell et al. (US Application Publication No. 2002/0090392, cited in PTO-892).

Abraham et al. teaches fermenting cows' milk (which comprises whey proteins) with kefir grains to yield a composition comprising fermented milk and kefir grains (page

328, paragraph 3; page 329, paragraph 8). Abraham et al. teaches that kefir grains inherently comprise **numerous** microorganisms, including several species of *Lactobacillus*, other bacteria, and yeast, in a matrix of protein and polysaccharide (page 327, paragraph 1).

Abraham et al. does not expressly disclose *Lactobacillus* strains R2C2, INIX, ES1 and K2, *Candida kefyr*, *Candida norvegensis* (instant claim 1). Abraham et al. does not expressly disclose a micelle or taxane (instant claim 1).

Micheli et al. discloses that kefir grains inherently comprise a water-soluble branched glucogalactan (*i.e.*, a heteropolysaccharide comprising glucose and galactose units) called kefiran (page 69, column 2, paragraph 2).

Maeda et al. discloses that kefiran inherently has a molecular weight of about 760,000 Daltons (abstract).

Jolly et al. teaches EPS' synthesized by lactic acid bacteria can therapeutically treat colon cancer, via short-chain fatty acids generated upon degradation of the EPS in the colon (p.372, first paragraph). Jolly et al. suggests performing additional oral administration studies to elucidate the known therapeutic effects of EPS', i.e. antitumor properties (p.372, first paragraph). Jolly et al. teaches yoghurts are produced by fermentation of milk with EPS-producing strains *Lactobacillus delbrueckii* subsp. Bulgaricus (p.368, *Challenges for the dairy industry*, first paragraph).

Campbell et al. teaches as discussed above.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' R2C2 strain of *Lactobacillus* differs, and if

so to what extent, from the *Lactobacillus* strains discussed in Abraham et al. Accordingly, it has been established that the prior art strains, which have the same genus designation, can ferment whey, and are isolated from kefir grains, demonstrates a reasonable probability that it is either identical or sufficiently similar to the claimed R2C2 strain that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

Furthermore, the Office is not equipped to conduct experimentation in order to determine whether or not the composition of Abraham et al. comprises each and every type of microorganism recited in claim 1. Accordingly, it has been established that the prior art composition, which is made in the same manner as the instant composition and, according to Abraham et al., comprises numerous different bacterial species as well as yeast, demonstrates a reasonable probability that it is either identical or sufficiently similar to the composition in claim 1 that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

Merely because a characteristic of a known strain is not disclosed in a reference does not make the known strain newly patentable. The R2C2 strain possesses inherent characteristics which might not be displayed in the tests used in the reference, even if the R2C2 strain and the strains of Abraham et al. are identical.

Based on the teachings of the MPEP and KSR above, by employing the rationale in (B) simple substitution of one known element for another to obtain predictable results

and (G) some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention; one having ordinary skill in the art would have been motivated to formulate a composition comprising a micelle such as a liposome, an exopolysaccharide produced from *Lactobacillus* strains R2C2, INIX, ES1 and K2 and taxane. Abraham et al. teaches the kefir compositions comprise exopolysaccharides, i.e. kefiran and from Jolly et al., one would know that EPS' from lactic acid bacteria can be useful in treating cancer. Thus, one would be motivated to formulate a composition comprising the EPS' from lactic acid bacteria such as the EPS containing kefir compositions taught by Abraham et al. with other anti-cancer agents such as 5-FU and taxane in micelles like liposomes as taught by Campbell et al.

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teaching of the prior art.

Claims 1, 4-6, 19, 29, 30 and 40 are rejected under 35 U.S.C. 103(a) as being obvious over Hartkorn (1980, U.S. Patent 4,209,389) as evidenced by Micheli et al. and Maeda et al. in view of Jolly et al. (*Antonie van Leeuwenhoek*, cited in PTO-892) and in further view of Campbell et al. (US Application Publication No. 2002/0090392, cited in PTO-892).

Hartkorn teaches fermenting defatted milk (which inherently comprises whey proteins) with kefir grains, yielding a "spherical coherent culture," and adding water to

said spherical coherent culture and centrifuging the resulting mixture (column 3, lines 19-31).

Micheli et al. is cited solely as evidence that kefir grains inherently comprise a water-soluble branched glucogalactan (*i.e.*, a heteropolysaccharide comprising glucose and galactose units) called kefiran (page 69, column 2, paragraph 2).

Maeda et al. is cited solely as evidence that kefiran inherently has a molecular weight of about 760,000 Daltons (Abstract).

The discussion of the inherent properties of the composition of Abraham et al. (*i.e.*, the strain designation of the bacteria and the number of microorganisms in the kefir grains) also applies to this rejection over Hartkorn.

Based on the teachings of the MPEP and KSR above, by employing the rationale in (B) simple substitution of one known element for another to obtain predictable results and (G) some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention; one having ordinary skill in the art would have been motivated to formulate a composition comprising a micelle, an exopolysaccharide produced from *Lactobacillus* strains R2C2, INIX, ES1 and K2 and taxane. Micheli et al. discloses that the kefir compositions comprise exopolysaccharides, i.e. kefiran. Thus, one would know that the composition taught by Hartkorn inherently comprises EPS'. From Jolly et al., one would know that EPS' from lactic acid bacteria can be useful in treating cancer. Thus, one would be motivated to formulate a composition comprising the EPS' from lactic acid bacteria such as the EPS

containing kefir compositions taught by Hartkorn et al. with other anti-cancer agents such as 5-FU and taxane in micelles such as liposomes as taught by Campbell et al.

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teaching of the prior art.

Claims 1, 4-6, 19, 29, 30 and 40 are rejected under 35 U.S.C. 103(a) as being obvious over Hori et al. (US Patent No. 5,132,122, cited in PTO-892) taken in light of Micheli et al. and Maeda et al. in view of Jolly et al. (*Antonie van Leeuwenhoek*, cited in PTO-892) and in further view of Campbell et al. (US Application Publication No. 2002/0090392, cited in PTO-892).

Hori et al. teach adding kefir grains to cow's milk (which inherently comprises whey proteins), allowing fermentation to occur, and centrifuging the fermentate to yield a whey and a precipitate (column 6, lines 25-37); it is this precipitate, which comprises the microorganisms and insoluble proteins, that anticipates the instantly claimed composition.

Micheli et al. is cited solely as evidence that kefir grains inherently comprise a water-soluble branched glucogalactan (*i.e.*, a heteropolysaccharide comprising glucose and galactose units) called kefiran (page 69, column 2, paragraph 2).

Maeda et al. is cited solely as evidence that kefiran inherently has a molecular weight of about 760,000 Daltons (Abstract).

The discussion of the inherent properties of the composition of Abraham et al. (*i.e.*, the strain designation of the bacteria and the number of microorganisms in the kefir grains) also applies to this rejection over Hori et al.

Based on the teachings of the MPEP and KSR above, by employing the rationale in (B) simple substitution of one known element for another to obtain predictable results and (G) some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention; one having ordinary skill in the art would have been motivated to formulate a composition comprising a micelle, an exopolysaccharide produced from *Lactobacillus* strains R2C2, INIX, ES1 and K2 and taxane. Micheli et al. discloses that the kefir compositions comprise exopolysaccharides, i.e. kefiran. Thus, one would know that the composition taught by Hori et al. inherently comprises EPS'. From Jolly et al., one would know that EPS' from lactic acid bacteria can be useful in treating cancer. Thus, one would be motivated to formulate a composition comprising the EPS' from lactic acid bacteria such as the EPS containing kefir compositions taught by Hori et al. with other anti-cancer agents such as 5-FU and taxane in micelles such as liposomes as taught by Campbell et al.

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teaching of the prior art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4-6, 29-30 and 40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5, 12-14, 16-18, 27-29, 53, 70-74 and 76-79 of copending Application No. 10/499313 in view of Campbell et al. (US Application Publication No. 2002/0090392, cited in PTO-892).

Claims 1, 2, 5, 12-14, 16-18, 27-29, 53, 70-74 and 76-79 of the '313 application are drawn to a formulation comprising a concentrated "agglomerate" of fermented whey proteins. Claim 2 of the '313 application recites that the whey protein is produced from at least two microorganisms, including *Lactobacillus* strains R2C2, INIX, ES1 and K2 (claim 28 of the '313 application). Claim 12 of the '313 application recites that the formulation includes polysaccharides bonded to the proteins. The '313 application discloses the fermentation by-product comprises polysaccharides, including EPS,

(paragraphs 0038-0039 of the specification). The '313 application discloses the protein containing the EPS is formulated at concentrations ranging from 0.001% to 1% (column 17, example 26, paragraph 0182), i.e. critical micellar concentrations identical to the instant disclosure (see instant specification, column 4, example 1, paragraph 0056). The '313 application discloses the EPS containing protein is formulated with 5-fluoro uracil to treat colon cancer (column 20, example 37). Thus, the '313 application discloses an EPS micelle, i.e. a "delivery system" comprising 5-FU, wherein the EPS was produced by bacterial *Lactobacillus* strains R2C2, INIX, ES1 and K2.

The '313 application does not expressly disclose taxane (instant claim 40).

Claims 1, 4-6, 29-30 and 40 are drawn to a delivery "system" comprising a micelle comprising an EPS and an active agent, i.e. taxane or 5-FU.

Campbell et al. teaches as discussed above.

Based on the teachings of the MPEP and KSR above, by employing the rationale in (B) simple substitution of one known element for another to obtain predictable results; one having ordinary skill in the art would have been motivated to formulate a composition comprising a micelle, an exopolysaccharide produced from *Lactobacillus* strains R2C2, INIX, ES1 and K2 and taxane. The '313 application teaches a micelle comprising an EPS produced from the aforementioned strains to treat cancer, specifically with 5-FU as the therapeutic agent. Campbell et al. teaches that 5-FU and taxane are both anti-cancer agents and can be formulated with micellar structures, such as liposomes. Thus, one having ordinary skill in the art would be motivated to substitute

the 5-FU taught in the '313 application for taxane since they are taught as having similar functionality in similar formulations.

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teaching of the prior art.

This is a provisional obviousness-type double patenting rejection.

Conclusion

In view of the rejections to the pending claims set forth above, no claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. BAHAR SCHMIDTMANN whose telephone number is 571-270-1326. The examiner can normally be reached on Mon-Thurs 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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